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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,338	06/26/2000	Han-Cheng Zhang	ORT-1238	2229

7590

01/09/2004

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EXAMINER

MOHAMED, ABDEL A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/603,338	ZHANG ET AL.	
Examiner	Art Unit	
Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- No period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 1023.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3,5. 6) ☐ Other: _____

DETAILED ACTION

ACKNOWLEDGMENT OF IDS, AMENDMENT, SEQUENCE LISTING, RESPONSE TO RESTRICTION REQUIREMENT AND STATUS OF THE CLAIMS

1. The information disclosure statements (IDS) and Form PTO-1449 filed 2/7/01, 2/14/01 and 12/10/01, the amendment filed 10/16/02, the sequence listing filed 12/24/02 and the response to the restriction requirement filed 10/23/03 are acknowledged, entered and considered. However, some of the references provided by Applicant were not considered. Reference submitted on 12/10/01 is a PCT search report, which does not contain a place of publication, and reference submitted 2/14/01 is a copending application 09/603,231, which has not been published or patented, therefore, reference to it cannot be printed in case the present application is allowed. References 09/603,229 and 09/599,826 have been considered as U.S. Patent Nos. 6,365,617 and 6,630,451, respectively (See USPTO-Form 892 provided herewith as Paper No. 17). Claims 1-23 are now pending in the application.

ELECTION WITHOUT TRAVERSE

2. Claims 1-23 were originally filed. The claims were subject to a Restriction Requirement/Species Election in the Office action mailed 9/27/01, Paper No. 4. Applicant elected Group III, claims 1-10, 23 and 19-22, without traverse without electing species. The species election requirement was reinstated in the Office action mailed 10/1/03, Paper No. 15. In response to the species election, Applicant elected as Ultimate specie, the chemical structure found in Table 1, on page 16 and on page 20 in

the instant specification. However, upon further consideration, the requirement for species election is withdrawn. Thus, the Office action is directed to the merits of claims 1-10, 23 and 19-22 (Group III) as *per* elected invention. Claims 11-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

The Restriction Requirement is made Final.

In response to the above Final, Applicant is advised to cancel the non-elected invention.

OBJECTIONS TO TRADEMARKS AND THEIR USE

3. The use of the trademarks "PrepPak®" and "Bondapak®" have been noted in this application. These trademarks have not been capitalized, they should be capitalized whenever they appear and be accompanied by the generic terminology. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner which might adversely affect their validity as trademarks.

Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademark. These description requirements are made because the nature and composition of article denoted by trademarks can change and affect the adequacy of the disclosure.

CLAIMS REJECTION-35 U.S.C. § 112^{2nd} PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-10 and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 23 are indefinite in the recitation "....selected from...." and ".....selected from one or more...". Similarly claims 6 and 7 are indefinite in the recitation ".....selected from...." because it is not clear if Applicant intends a Markush format. If Applicant intends to use a Markush format, then, the Office recommends the use of the phrase "....selected from the group consisting of....." with the use of connective words such as "and" or "or" in listing species.

Claims 1-4 and 23 are also indefinite in the recitation "optionally" because if an ingredient, a step, or other structural element is truly optional i.e. its presence is not necessary for attainment of the result that is an object of the invention, then recitation thereof does not belong in the claims.

HEADINGS FOR STATUTORY BASIS OF DOUBLE PATENTING

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis

added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

REJECTION UNDER 35 U.S.C. § 101 FOR DOUBLE PATENTING

6. Claims 1-10 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of prior U.S. Patent No. 6,630,451. Both sets of claims are identical word for word. This is a double patenting rejection.

HEADINGS FOR NONSTATUTORY DOUBLE PATENTING

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

OBVIOUSNESS-TYPE DOUBLE PATENTING

8. Claim 1-10 and 19-23 are rejected under the under the judicially created doctrine of obviousness-type as being unpatentable over claims 1-7 and 16-19 of U.S. Patent No. 6,365,617 in view of Hoekstra et al. (U.S. Patent No. 6,017,890). Although, the conflicting claims are not identical, they are not patentably distinct from each other because the '617 patent discloses a compound of the formula I and method of treating a condition mediated by thrombin receptor (PAR-1) with the limitations of claims 1-7 and 16-19 of the instant invention, but devoid of A1 and A2, which are D-or L-amino acids selected from the group consisting of alanine, cysteine, serine, leucine, phenylalanine, etc. However, Hoekstra et al. teach a compound with A1 and A2, which are D- or L-amino acids selected from the group consisting of alanine, cysteine, serine, leucine, phenylalanine, etc. (See e.g., col. 1, lines 8-35 and claim 1). It would have obvious to one of ordinary skill in the art at the time the invention was made to combine and substitute the A1 and A2, which are D- or L-amino acids of Hoekstra et al. in the

compound of the formula I of '617 patent with the limitations thereof but devoid of A1 and A2 of said '617 patent since Hoekstra et al. on col. 1, lines 29-35 states, "Hence, antagonists of the thrombin receptor based on SFLIRN are useful in antagonizing these protease-activated receptors and as such may be used to treat platelet mediated thrombotic disorders." Thus, in view of this statement, one of ordinary skill in the art would have been motivated to combine and substitute the A1 and A2 of Hoekstra et al. in the compound formula I with all limitations of '617 patent but devoid of A1 and A2 in order to achieve the express advantages, as noted by Hoekstra et al. of antagonists of thrombin receptors based on SFLIRN which are useful for the same purpose of the instantly claimed invention as claimed in claims 19-22 of a method of treating a condition mediated by thrombin receptor (PAR-1). Therefore, one of ordinary skill in the art would envision both sets of claims as one invention, and as such, it is an obvious variation of each other.

PROVISIONAL REJECTION OF OBVIOUSNESS TYPE DOUBLE PATENTING

9. Claims 1-10 and 19-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 10-12 of copending Application No. 09/603,231. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention (Serial No.09/603,338) is directed to the method of treating a condition mediated by thrombin receptor (PAR-1) by administering an effective amount of the

compound recited in claim 1 (formula I) and to a process of making said compound and a pharmaceutical formulation thereof. Similarly, Serial No. 09/603,231 is directed to compounds of Formula I and II and method of making said compounds and to pharmaceutical formulations thereof. The only difference between the instant invention claims and the claims of copending Application Serial No. 09/603,231 is the scope of the claims in which the instantly claimed invention is specifically directed to administer the compound of formula I in a method of treating a condition mediated by thrombin receptor with specific dosages claimed as recited in claims 19-22 while the copending application claims is directed broadly to compounds of formula I and II and pharmaceutical formulations thereof. Claims 5-7 of the instantly claimed invention is identical with claims 5-7 of copending application Serial No. 09/603,231. The difference of both application is that R_2 is specifically claimed in claim 1 of copending application while in the instantly claimed invention of claim 1 is not claimed. Thus, because of this R_2 and R_3 , R_4 and R_5 of claim 1 of the instant claimed invention is R_3 and R_4 , R_5 and R_6 of claim 1 of copending application, respectively. Thus, both inventions basically have the same compounds, except for the arrangement of Rs, and the invention of the instantly claimed invention appears to be narrower in scope than that of the copending application Serial No. 09/603,231 which is broader because the copending application claims and/or encompasses the use of the compounds in pharmaceutical formulations without specifying for what (i.e., claim 9 is directed to a pharmaceutical composition comprising a pharmaceutically acceptable carrier and a compound of claim 1). Thus, since both inventions claim pharmaceutical formulation comprising substantially the

same compounds thereof for the same purposes; it is an obvious variation to use or adapt either the broader scope or the specific because both pharmaceutical formulations are intended for treatment of thrombin receptor antagonists as disclosed in their abstracts and summary of the inventions, respectively. Therefore, both inventions are an obvious variation of the other since the same compounds are used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other. Thus, absent of showing in the claim(s), it is apparent that the administration of the compounds claimed for a method of treating a condition mediated by thrombin receptor (PAR-1) and pharmaceutical formulations thereof of current claims are an obvious variation of the copending application Serial No. 09/603,231 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

CONCLUSION AND FUTURE CORRESPONDENCE

10. Claims 1-10 and 19-23 are rejected and claims 11-18 are withdrawn as non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Mohamed/AAM

December 31, 2003



ROBERT A. WAX
PRIMARY EXAMINER